PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	RICHARD F. MURPHY	Confirmation No.:	9920
Serial No.:	10/667,909	Examiner:	C. KOHARSKI
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Docket No.:	1001.1530101	Customer No.:	28075

Title: SURFACE MODIFIED REINFORCING MEMBER FOR MEDICAL DEVICE AND METHOD FOR MAKING SAME

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Thu H. Le-To — DECEMBER 26, 2007 (Date)

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on October 18, 2007, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed November 29, 2007. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $500.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Richard F. Murphy, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014541, Frame 0833.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-56 remain pending, of which claims 1-40 have been withdrawn from consideration. Claims 41-56 remain under consideration.

Claim 41 stands finally rejected under 35 U.S.C. § 102(b) as being anticipated by *Cohen* (U.S. Patent 5,330,521).

Claims 41-56 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Parisi et al.* (U.S. Patent Publication 2001/0027310) in view of *Cohen.*

Claims 41-56 stand appealed.

IV. STATUS OF AMENDMENTS

No amendments subsequent the final rejection of May 18, 2007 have been presented.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to a method of making a reinforcing member that includes treating at least the portion of the surface of one or more structural elements used to create the reinforcing member to provide increased surface area, or to provide a roughened or textured surface on at least a portion of the finished reinforcing member and to medical devices that include such a member. See specification at page 1, lines 22-26 and page 1 line 31-page 2, line 2.

Turning now to independent claim 41, which is directed to a medical device (numeral 10 in Figure 1; page 4, lines 11-12) including a reinforcing member (numeral 32 in Figure 2A, page 5, line 20), the medical device formed by the following process: providing one or more metallic filaments adapted and configured to be made into the reinforcing member for the medical device (page 7, lines 10-14), the one or more metallic filaments including a metallic surface having a portion with an initial surface area; treating at least the portion of the surface of the one or more metallic filaments to provide a final surface area that is greater than the initial surface area (page 9, lines 20-24); creating the reinforcing member using the one or more metallic filaments(page 7, lines 10-14); and incorporating the reinforcing member into the construction of the medical device (page 11, lines 4-8).

Claim 42, which depends from claim 41, is directed to wherein the medical device is a catheter (numeral 10 in Figure 1; page 4 at lines 12-13).

Claim 43, which depends from claim 41, is directed to wherein the reinforcing member includes an outer surface, an inner surface, and a lumen (numeral 18 in Figure 2A; page 5, lines 7-11) extending there through.

Claim 44, which depends from claim 43, is directed to wherein incorporating the reinforcing member into the construction of the medical device includes connecting an outer layer (numeral 30 in Figure 2A) to the outer surface of the reinforcing member (page 11, lines 25-28).

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* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting. For simplicity and because the application was restricted to the embodiment of Figures 2 and 3, the references to the specification and drawings are primarily directed towards Figures 2 and 3 and the corresponding description in the specification, but this is not meant to be limiting as support may be found throughout the specification and in many of the Figures.

Claim 45, which depends from claim 44, is directed to wherein the outer layer (numeral 30 in Figure 2A) comprises a polymer material (page 6, lines 1-3).

Claim 46, which depends from claim 43, is directed to wherein incorporating the reinforcing member into the construction of the medical device includes connecting an inner layer (numeral 34 in Figure 2A) to the inner surface of the reinforcing structure (page 11, lines 25-28).

Claim 47, which depends from claim 46, is directed to wherein the inner layer (numeral 34 in Figure 2A) comprises a polymer material (page 6, lines 1-3).

Claim 48 is directed to a medical device (numeral 10 in Figure 1; page 4, lines 11-12) comprising: a reinforcing member (numeral 32 in Figure 2A, page 5, line 20) including a metallic filament (page 7, lines 10-14) that includes a metallic surface that includes a portion that has been treated to provide an increased surface area relative to a surface area of the portion prior to treatment (page 9, lines 20-24); one or more polymer structures (numerals 30 and 34 in Figure 2A) connected to the treated portion of the surface of the metallic filament (page 11, lines 25-28); wherein the increased surface area on the portion of the surface of the metallic filament of the reinforcing member allows for a mechanical bond between the reinforcing member and the one or more polymer structures (page 9, lines 27-30).

Claim 49, which depends from claim 48, is directed to wherein the medical device is a catheter (numeral 10 in Figure 1; page 4 at lines 12-13).

Claim 50, which depends from claim 48, is directed to wherein the reinforcing member includes an outer surface, an inner surface, and a lumen extending there through (numeral 18 in Figure 2A; page 5, lines 7-11).

Claim 51, which depends from claim 50, is directed to wherein the one or more polymer structures comprises an outer polymer layer (numeral 30 in Figure 2A; page 6, lines 1-3) connected to the outer surface of the tubular reinforcing member (page 11, lines 25-28).

Claim 52, which depends from claim 50, is directed to wherein the one or more polymer structures comprises an inner polymer layer (numeral 34 in Figure 2A) connected to the inner surface of the tubular reinforcing member (page 11, lines 25-28).

Claim 53 is directed to a catheter (numeral 10 in Figure 1; page 4, lines 11-12) comprising an elongated tubular body (numeral 12 in Figure 1) having a proximal portion, a distal portion, and a lumen extending there through (numeral 18 in Figure 2A; page 5, lines 7-

11), the tubular body comprising: a metallic reinforcing member (numeral 32 in Figure 2A, page 5, line 20) including a metallic surface, wherein at least a portion of the surface has been treated to provide an increased surface area relative to a surface area of the portion prior to treatment (page 9, lines 20-24); a member made of a polymer material (numeral 30 or 34 in Figure 2A; page 6, lines 1-3), the member being connected to the surface (page 11, lines 25-28); wherein increased surface area of the reinforcing member allows the polymer material to create a mechanical bond with the surface (page 9, lines 27-30).

Claim 54 is directed to a catheter (numeral 10 in Figure 1; page 4 at lines 12-13), comprising: a braid (numeral 32 in Figure 2A, page 7, lines 13-18) including a plurality of metallic braid filaments each including a metallic surface, wherein a portion of the surface of the filaments is chemically etched to provide a roughened surface (page 9, lines 20-24); and a polymer member (numeral 30 34 in Figure 2A) connected to the roughened surface (page 11, lines 25-28).

Claim 55, which depends from claim 41, is directed to wherein the reinforcing member includes a braid (numeral 32 in Figure 2A, page 7, lines 13-18).

Claim 56, which depends from claim 41, is directed to wherein the reinforcing member includes a coil (numeral 32 in Figure 2A, page 7, lines 13-18).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claim 41 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by *Cohen* (U.S. Patent 5,330,521)?

2. Whether claims 41-56 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over *Parisi et al.* (U.S. Patent Publication 2001/0027310) in view of *Cohen*?

VII. ARGUMENT

A. CLAIM 1 IS PATENTABLE OVER COHEN UNDER 35 U.S.C. § 102 AND CLAIMS 41-45 ARE PATENTABLE OVER PARISI ET AL. IN VIEW OF COHEN UNDER 35 U.S.C. § 103

1. Prior art references must teach or suggest all of the claimed limitations.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Both rejections rely on *Cohen* for teaching an etching process. And *Cohen* does, in fact, teach an etching process. The point of contention between Appellant and Examiner is whether the etching process of Cohen results in an increase in surface area. As Appellant shows below, etching does not necessarily result in an increase of surface area and the particular processes described by Cohen likely reduce the surface area. Because Cohen does not teach an etching process that necessarily and inherently results in an increased surface area, all the claim elements are not present in the prior art. For example, independent claim 41 recites "treating at least the portion of the surface of the one or more metallic filaments to provide a final surface area that is greater than the initial surface area." The other independent claims include similar language regarding an increased surface area relative to that prior to treatment.

In the Final Office Action, the Examiner cites this portion of Cohen in support of the argument that Cohen discloses this element of the claimed inventions.

> A wire core having a varied diameter, as described above, may be manufactured, for example, by feeding a wire of uniform diameter through an etchant, such as an aqua regia, at varying speed. A length of wire having a smaller diameter may be manufactured by feeding the wire through the etchant at relatively slow speed so that the wire core is exposed to the etchant a sufficient time for the etchant to chemically etch the wire core to a predetermined diameter. The length of wire having the cross-sectional area which tapers from the smaller diameter to the larger diameter may be obtained by gradually increasing the speed of the wire through the etchant, thereby producing a wire core having a tapered diameter with no discontinuities.

Cohen, column 9, lines 30-45. The etching process described by Cohen tapers the guidewire. Tapering an elongate wire by material removal necessarily results in a decrease of surface area. The general formula for the surface area of a function rotated about the x-axis is: $2\pi\int_a^b f(x)\sqrt{1+(f'(x))^2}\,dx$. Where the function describes a cylinder of uniform diameter having a radius of r_1 and length l, the formula reduces to $2\pi \cdot r_1 \cdot l$. Where the function describes

a cylinder uniformly tapering along a length of l from a radius of r_1 to a radius of r_2, the formula reduces to $2\pi \cdot l\left(\frac{(r_2 - r_1)}{2} + r_1\right)\sqrt{\frac{(r_1 - r_2)^2}{l^2} + 1}$. One can use these two formulas to compare surfaces areas of a wire before and after a tapering operation. For example, take a wire of 200 cm in length with a radius of 0.1 cm. Using the first formula, this wire has a surface area (exclusive of the ends) of approximately 126 square centimeters. If this wire is given a uniform taper so that the one end still has the 0.1 cm radius and the other has a 0.05 cm taper, the second formula gives a surface area of approximately 94 square centimeters, a significant reduction in surface area. As mentioned, this reduction of surface area holds true for the tapering of any elongate cylinder such as a wire. This makes intuitive sense; the calculus operation is, in essence, the summing up of the circumferences of all the circles that make up the cylindrical wire. If the wire is tapered, however, one is summing up successively smaller circumferences, which corresponds to a decrease in total surface area. This section of Cohen, therefore, cannot support a process step in which etching is used to increase the relative surface area.

Cohen mentions etching in another portion of the specification as well and for a different purpose. Cohen teaches:

> Any electrically insulating oxides or films that may be present on the surface of the wire core 22 must be substantially removed before forming the electrically conductive layer 24 on the wire core 22 in order to provide good electrical continuity between the wire core and the electrically conductive layer 24. An example of one technique for removing such oxides or films from the surface of the wire core 22 involves etching the wire core with an acid in an inert atmosphere, such as argon or nitrogen, before forming the conductive material thereon. The removal of such films and oxides also promotes mechanical adhesion between the conductive layer 24 and the surface of the wire core 22.

Cohen at column 6, lines 52- 65. Thus Cohen also teaches etching to clean oxides from the surface of the wire core to improve electrically continuity and to promote adhesion. However, removing oxides does not necessarily increase surface area and most likely decreases it. Oxides and films are more formal terms for rust and tarnish, which do not typically form uniformly and quite often leave the rusted and tarnished surface rougher (e.g. having more

surface area) than the surface when it was rust free. The removal of such oxides and films may therefore restore the surface to a smoother state having a reduced surface area. In the case where the presence of the oxides and films do not measurably increase the surface area, one must still recall that the etching process is a material removal process. The wire core is a cylinder, which will have a certain diameter prior to etching and a lesser diameter after etching. If the etching process does not actually make the surface smoother by the removal of the oxides, it still makes it smaller. The wire core after etching has the lesser diameter and will therefore have less surface area than it did prior to the etching process. An etching process that does not increase the surface roughness and merely removes oxides and films will improve the electrical continuity simply through the elimination of the oxides and films, which typically have more electrical resistance than the unoxidized metal core or conductive layer. Likewise, mechanical adhesion will be improved by the removal of materials that are either difficult to bond to or have a tendency to flake off. Cohen does using chemicals what a painter may do using a scraper: removes loose flakes of material and surface impurities. Neither the chemical etching process of Cohen nor the wall surface preparation process of a competent painter results in a rougher surface. This section of Cohen as well, therefore, cannot support a process step in which etching is used to increase the relative surface area.

Etching is a merely a method of removing material by chemical action. A material removal process may, as in the case of sanding a piece of wood, actually decrease the surface area. The same material removal process, depending on the specifics of the application, may be used to either increase or decrease the surface area of an object. For example, one may carve a stick by smoothing out its surface and thereby decrease the surface area of the stick or one may carve a stick by carving designs into the surface of the stick and thereby increase the surface area of the stick. In Cohen, an etching process is taught. But this etching process of Cohen, whether to taper the wire or to remove oxides and films, is not a process that can be shown to increase the surface area of the workpiece relative to its prior condition.

For this reason, Cohen does not teach each and every element set forth in claim 41, either expressly or inherently and Parisi et al. in view of Cohen does not teach or suggest all the claim limitations of claims 41-56.

B. CONCLUSION.

For the reasons stated above, claim 41 is not anticipated by Cohen; claims 41-56 are nonobvious over Parisi et al. in view of Cohen; and the Examiner's rejections of claims 41-56 under 35 U.S.C. §§ 102 and 103 should be overruled.

Respectfully submitted,

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By their Attorney,

Date: December 26, 2007

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VIII. CLAIMS APPENDIX

41. A medical device including a reinforcing member, the medical device formed by the following process:

providing one or more metallic filaments adapted and configured to be made into the reinforcing member for the medical device, the one or more metallic filaments including a metallic surface having a portion with an initial surface area;

treating at least the portion of the surface of the one or more metallic filaments to provide a final surface area that is greater than the initial surface area;

creating the reinforcing member using the one or more metallic filaments; and

incorporating the reinforcing member into the construction of the medical device.

42. The medical device of claim 41, wherein the medical device is a catheter.

43. The medical device of claim 41, wherein the reinforcing member includes an outer surface, an inner surface, and a lumen extending there through.

44. The medical device of claim 43, wherein incorporating the reinforcing member into the construction of the medical device includes connecting an outer layer to the outer surface of the reinforcing member.

45. The medical device of claim 44, wherein the outer layer comprises a polymer material.

46. The medical device of claim 43, wherein incorporating the reinforcing member into the construction of the medical device includes connecting an inner layer to the inner surface of the reinforcing structure.

47. The medical device of claim 46, wherein the inner layer comprises a polymer material.

48. A medical device comprising:

a reinforcing member including a metallic filament that includes a metallic surface that includes a portion that has been treated to provide an increased surface area relative to a surface area of the portion prior to treatment;

one or more polymer structures connected to the treated portion of the surface of the metallic filament;

wherein the increased surface area on the portion of the surface of the metallic filament of the reinforcing member allows for a mechanical bond between the reinforcing member and the one or more polymer structures.

49. The medical device of claim 48, wherein the medical device is a catheter.

50. The medical device of claim 48, wherein the reinforcing member includes an outer surface, an inner surface, and a lumen extending there through.

51. The medical device of claim 50, wherein the one or more polymer structures comprises an outer polymer layer connected to the outer surface of the tubular reinforcing member.

52. The medical device of claim 50, wherein the one or more polymer structures comprises an inner polymer layer connected to the inner surface of the tubular reinforcing member.

53. A catheter comprising an elongated tubular body having a proximal portion, a distal portion, and a lumen extending there through, the tubular body comprising:

a metallic reinforcing member including a metallic surface, wherein at least a portion of the surface has been treated to provide an increased surface area relative to a surface area of the portion prior to treatment;

a member made of a polymer material, the member being connected to the surface;

wherein increased surface area of the reinforcing member allows the polymer material to create a mechanical bond with the surface.

54. A catheter, comprising:

a braid including a plurality of metallic braid filaments each including a metallic surface, wherein a portion of the surface of the filaments is chemically etched to provide a roughened surface; and

a polymer member connected to the roughened surface.

55. The medical device of claim 41, wherein the reinforcing member includes a braid.

56. The medical device of claim 41, wherein the reinforcing member includes a coil.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None